

REMARKS/ARGUMENTS

This is in response to the Office Action mailed January 28, 2005. Claims 1, 4, 5 and 6 have been amended to improve form. The scope of the claims has not been narrowed. New claims 50-60 have been added. Support for new claims 50 and 51 can be found on page 7, lines 4-7 of the originally filed specification. Support for new claims 52 to 57 can be found in Table 4, rows 3 and 4. Support for new claims 58 to 60 can be found on page 9, lines 16-23. No new matter has been added. Independent claim 1 and its dependent claims 4-6, and 27-49 and independent claim 50 and its dependent claims 51-60 are currently pending and at issue.

Claim Rejections - 35 U.S.C. §102

Claims 1, 5, 6, 28 and 47-49 were rejected under 35 U.S.C. §102(e) as being anticipated by Hinz. The Examiner asserts that Hinz teaches calcium for the treatment of obesity and that a generic multiple vitamin is disclosed (column 8, line 65).

Hinz discloses a pharmacological therapy using Phentermine and/or Diethylpropion with an SSRI medication, Citalopram, to effectuate weight loss, appetite suppression and treatment of obesity, in conjunction with replacement of vitamins to counter nutritional deficiency (column 4, line 59-column 5, line 2). The consumption and addition of calcium is mentioned to assist in avoiding nutritional deficiency (column 4, lines 25-27), e.g., using 50 mg to 2,000 mg per day to prevent bone demineralization (column 6, lines 2-3).

To the contrary, the present invention is directed to the use of therapeutically effective amounts of calcium or calcium-containing products, such as dairy products, to bring about weight loss via a calcium-induced metabolic change. The therapeutically effective amount as recited in the claims is an amount of calcium sufficient to induce weight loss, prevent weight gain, and/or increase the metabolic consumption of adipose tissue in a mammal (page 7, lines 4-7). Examples for humans are at least about 773 mg of calcium intake per day, 57 servings of dairy per month, 1,346 mg of calcium intake per day, or 102 servings of dairy per month (Table 4, rows 3 and 4). Hinz does not teach such a method, explicitly or inherently. The use of pharmaceuticals and

calcium suggested by Hinz, especially in low amounts, would not necessarily and inevitably induce the metabolic change as recited in claim 1.

Accordingly, claims 1, 4-6, and 27-60 are not anticipated.

Claim Rejections - 35 U.S.C. §103

Claims 1, 4-6, and 27-49 were rejected under 35 U.S.C. §103(a) as obvious in light of Hinz. The Examiner asserts that Hinz also teaches 50-2,000 mg of calcium (claim 7). The Examiner further purports that as to the claimed food vehicles, such as spinach, or items that may be fortified with such, are well known to be a source of calcium in the diet, and that it would be obvious to substitute a food source for the multivitamin disclosed in Hinz, for the beneficial effect of the additional nutrient therein.

As set forth above, Hinz does not teach or suggest the use of calcium to induce weight loss. Nor would it be obvious to one skilled in the art to administer calcium or calcium-containing products, such as dairy products, and thereby to induce weight loss. Prior to Dr. Zemel's work, there was no recognition that high calcium dosages in the claimed food vehicles or the diet would be therapeutically effective to promote weight loss. The importance of maintaining high calcium intake during attempts to lose, maintain or control weight was previously unrecognized and was unexpected prior to Dr. Zemel's pioneering work.

Due to these unexpected results, there has been a significant shift in the scientific community and the food industry, which has supported and endorsed the methods of the present invention. The invention has achieved considerable public recognition and commercial success, as indicated by the attached documentation.

Page one of the attached material lists various clinical trials conducted by Dr. Zemel further showing the beneficial effects of consuming high calcium and dairy in accelerating the effects of weight loss in humans. Page two shows how the food industry has adopted the novel methods of the present invention, e.g., the label "3-A-Day Milk Cheese Yogurt, Burn more fat, lose weight" communicates the message that increasing dairy consumption to at least three servings a day supports weight loss. As set forth on page two, over 50 top U.S. retail chains have licensed the inventive methods and are promoting the inventive methods by placing labels with the weight loss

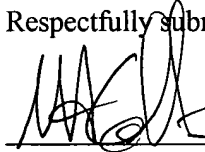
message on over 2.5 billion dairy packages to date. Pages three, four and five evidence various examples of leading industry packages and consumer advertisements. Page six provides testimonials about the inventive methods from notable health professional associations. The American Academy of Family Physicians refers to "dairy nutrition and its contribution to weight management." The National Medical Association recognizes that "[s]ome of the information that was presented today shows a clear beneficial relationship between the daily intake of three to four servings of dairy products and the reduction of obesity." The American Dietetic Association praises Dr. Zemel's work in that "[i]t has been exciting to see how emerging research on the role of calcium and dairy products adds to the body of knowledge about preventing and treating obesity [and t]his information provides additional tools for dietetics professionals to use in their day-to-day practice."

Accordingly, claims 1, 4-6, and 27-60 are not obvious.

Applicants respectfully submit that their application is now in condition for allowance.

Should any questions remain, please contact the undersigned.

Respectfully submitted,



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